K133204

510(k) Summary

MAY 0 5 2014

SUBMITTER INFORMATION:

SPSmedical Supply Corp.
a division of Crosstex International
6789 West Henrietta Road
Rush, NY 14543 U.S.A.
Phone: (800) 722-1529 Fax: (585) 359-0167

Contact: Michael Nolan
Research and Development Coordinator

Date of Summary: May 5, 2014

DEVICE INFORMATION:

Device Trade Name:	AirView™ II Bowie Dick Test Pack
Common Name:	Bowie Dick Test Pack
Classification Name:	Indicator, Physical/Chemical Sterilization Process 21 CFR § 880.2800
Review Panel:	General Hospital
Product Code:	JOJ
Device Class:	2

PREDICATE DEVICE:

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets K130211

DEVICE DESCRIPTION:

Functionality—The AirView™ II Bowie Dick Test Pack is designed for routine testing of 134°C (273°F) prevacuum steam sterilizers. The Bowie Dick test is part of the daily release criteria for any prevacuum steam sterilizer. It may also be used after sterilizer installation, relocation, malfunction, after major repairs and after sterilization process failures. The AirView™ II Bowie Dick Test Pack should always be run in an empty chamber.

Scientific Concepts—The Bowie Dick Test should be run only after the chamber has been preheated. It is a means of detecting air leaks in gaskets or chamber piping, poor air removal and subsequent steam penetration. The AirView™ II Bowie Dick Test Pack has proven safe and effective as a replacement for the standard Bowie Dick Towel Pack through validated performance testing.

Physical Characteristics—The AirView™ II Bowie Dick Test Pack consists of layers of paper with an air removal indicator placed in the center of the stack all placed within an exterior containment box. A process indicator label placed on the containment box alerts users if a pack has been exposed to the sterilization process. The approximate dimensions of the pack are 3-3/4" x 5/8" x 5". The air removal indicator within the AirView™ II Bowie Dick Test Pack should be retained as a permanent record while the remainder of the pack can be discarded with regular waste according to local legislation, recycling land filling or incineration. None of the AirView™ II Bowie Dick Test Packs components are made from lead.

Performance Characteristics—The AirView™ II Bowie Dick Test Pack performs substantially equivalent to the AAMI Standard Towel Pack when tested in conformance with the FDA guidance document for Chemical Indicators and ANSI/AAMI/ISO 11140-5.

INTENDED USE:

The AirView™ II Bowie Dick Test Pack is intended for the daily air removal efficacy testing of prevacuum steam sterilizers. It may also be used after sterilizer installation, relocation, malfunction, after major repairs and after sterilization process failures.

510(k) Summary (Continued)

TECHNICAL CHARACTERISTICS:

The outer box and layers of paper within the AirView™ II Bowie Dick Test Pack provide resistance to air removal and subsequent steam penetration of prevacuum steam sterilizers. The air removal indicator sheet within the pack offers clear evidence of sterilizer performance. The external process indicator alerts users when a pack has seen the sterilization process.

RECOMMENDED STORAGE CONDITIONS:

Store in a cool, dry place (15-30°C).

NON-CLINICAL TESTING:

Validation of the AirView™ II Bowie Dick Test Pack included performance testing in steam and dry heat, porosity of the indicator material, biocompatibility, and interfering substances (acid/base) on multiple lots of indicators. All results from testing meet the predetermined acceptance criteria. All testing followed the FDA Guidance document for Industry and FDA Staff entitled, "Premarket Notification [510(k)] Submissions for Chemical Indicators," issued on December 19, 2003.

Performance Steam— The cycle selected for validation is the commonly used prevacuum Bowie Dick cycle of 134°C for 3.5 minutes exposure. Pass cycles consisted of an air removal phase drawing a complete vacuum. The temperature limits were 0.5°C or less within the test pack when compared to the drain temperature during the exposure phase. Fail cycles utilized a modified air removal phase as allowed by the FDA guidance document to achieve the standard fault condition. By not completely removing the air from the chamber the residual air becomes entrapped within the test pack and creates a 2-3°C lower temperature in the center of the test pack when compared to the drain at the start of the last minute of the exposure phase. The results from testing demonstrated that the AirView™ II Bowie Dick Test Pack turns a uniform dark brown/black color when subjected to the standard pass cycle and turns a non-uniform color when subjected to the standard fault condition.

Performance Dry Heat—Results from dry heat testing demonstrated that the indicators require the presence of steam molecules in order to turn to their specified endpoint color.

Indicator Porosity—Results documented the porosity of the indicator material which meet the predetermined acceptance criteria.

Biocompatibility—Although the AirView™ II Bowie Dick Test Pack is intended to be run in an empty chamber SPSmedical and Crosstex International decided to run biocompatibility testing to address concerns of leaching. Biocompatibility testing concluded the indicators to be non-toxic.

Interfering Substances or Conditions—Testing verified that the indicators in their unprocessed form are not sensitive to an acidic or basic environment. Testing verified that the indicators in their processed form are not sensitive to an acidic or basic environment.

Shelf Life—When properly stored the AirView™ II Bowie Dick Test Pack maintains a shelf life of three (3) years from the date of manufacture. The expiration date is located on every pack. Post processing indicator stability has been documented to exceed two (2) years when properly stored.

SUBSTANTIAL EQUIVALENCE DISCUSSION

SPSmedical has identified the AirView™ Bowie Dick Test Pack & AirView™ Bowie Dick Indicator Sheets (K130211) as the (primary) predicate device. We believe the predicate device to be substantially equivalent to the AirView™ II Bowie Dick Test Pack which is the subject of this submission in terms of their intended use and functional characteristics in determining the efficacy of air removal in prevacuum steam sterilizers. See a comparison of the subject device to the predicate device (K130211) in Table 1.

510(k) Summary (Continued)

PREDICATE I.D.:

Trade Name:	SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets
Model No.:	SBD-030 (for Test Pack) & BDS-050 (for Sheets)
Submitter/holder:	SPSmedical Supply Corp. 6789 West Henrietta Road Rush, NY 14543 U.S.A. Phone: (585) 359-0130 Fax: (585) 359-0167
510(k) No.:	K130211

COMPARISON OF INDICATIONS FOR USE (IFU):

Predicate Device—The AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets are designed to detect the presence of residual air in prevacuum steam sterilizers. When tested in a prevacuum sterilizer operating at 134°C the indicator will demonstrate a uniform color change from cream or blue to dark brown/black when proper sterilization conditions have been met and no air is detected. It is designed to be used for daily Bowie Dick testing of steam sterilizers as described in ANSI/AAMI ST79.

Subject Device—The AirView™ II Bowie Dick Test Pack is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C for 3.5 minutes. The indicator sheet within the AirView™ II Bowie Dick Test Pack will demonstrate a uniform color change from blue to dark brown/black when proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C (+1°/-0°C) temperature difference between the center of the towel pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the AirView™ II Bowie Dick Test Pack will demonstrate a non-uniform color change.

Discussion—When compared to the predicate device the subject device has a similar IFU. They are made of similar package materials, they have the same intended use and they meet the same performance requirements.

DESIGN DIFFERENCES PREDICATE VS. SUBJECT DEVICE:

As stated in Table 1 both devices are Bowie Dick Test Packs. There are two (2) variations in the design of the packs. First, the subject device is smaller in size than the predicate and secondly, the subject device does not require the use of a foam insert within the pack. These differences do not change the Intended Use of the device.

FUNCTIONAL CHARACTERISTICS:

The AirView™ II Bowie Dick Test Pack is designed to detect the presence of residual air in prevacuum steam sterilizers. The layers of paper within the pack provide resistance to steam penetration and trap residual air which is difficult for marginally performing prevacuum sterilizers to remove. The pack is a reliable tool used for the daily monitoring of air removal in prevacuum steam sterilizers and provides a clear visual indication if residual air was left in the chamber during sterilization. The indicator sheet changes from its initial color (blue or cream) to a uniform dark brown/black signal color under proper sterilization and air removal conditions. A failure would result in a non-uniform color change on the indicator sheet.

510(k) Summary (Continued)

DISCUSSION:

SPSmedical is claiming substantial equivalence for its AirView™ II Bowie Dick Test Pack to the AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets (K130211) based on test data obtained during validation studies.

We have demonstrated with testing that the AirView™ II Bowie Dick Test Pack performs consistently with results which indicate that the indicator is sensitive enough to detect when enough air is left within the sterilizer chamber to create a 2°C or greater temperature difference in the test pack as compared to the sterilizer chamber when running prevacuum Bowie Dick cycles. Under these conditions, the indicator sheet would demonstrate a non-uniform color change. The AirView™ II Bowie Dick Test Pack is also comparable to other commercially available Bowie Dick test packs cleared by the FDA.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

The AirView™ II Bowie Dick Test Pack has the same intended use and characteristics as the primary predicate device (K130211). They both provide a visual indication that proper air removal and steam penetration conditions have been met within the sterilizer's chamber. Both products are comprised of paper sheets, a containment box, external chemical indicator label and printed indicator sheet.

Because the ability to perform its intended function has been shown through validated testing, the SPSmedical AirView™ II Bowie Dick Test Pack raises no issues related to safety or effectiveness. See Table 1 for a substantial equivalence comparison. SPSmedical believes that the SPSmedical AirView™ II Bowie Dick Test Pack is substantially equivalent to the predicate device because it has the same intended use, technical characteristics and performance.

TABLE 1—COMPARISON OF THE SUBJECT DEVICE TO THE PREDICATE

Element	Subject Device	Predicate (K130211)
Intended Use	Air Removal Indicator	Air Removal Indicator
Indications for Use	The AirView™ II Bowie Dick Test Pack is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C for 3.5 minutes. The indicator sheet within the AirView™ II Bowie Dick Test Pack will demonstrate a uniform color change from blue to dark brown/black when proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C (+1° /-0°C) temperature difference between the center of the towel pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the AirView™ II Bowie Dick Test Pack will demonstrate a non-uniform color change.	The AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick indicator sheets are designed to detect the presence of residual air in prevacuum steam sterilizers. When tested in a prevacuum sterilizer operating at 134°C the indicator will demonstrate a uniform color change from cream or blue to dark brown/black when proper sterilization conditions have been met and no air is detected. It is designed to be used for daily Bowie Dick testing of steam sterilizers as described in ANSI/AAMI ST79.
Device Design	Bowie Dick Test Pack	Bowie Dick Test Pack or Sheet

Package Materials	The AirView™ II Bowie Dick Test Pack consists of layers of paper with an air removal indicator placed in the center of the stack all placed within an exterior containment box. A process indicator label placed on the containment box alerts users if a pack has been exposed to the sterilization process. The approximate dimensions of the pack are 3-3/4" x 5/8" x 5".	The AirView™ Bowie Dick Test Pack consists of layers of paper, a foam insert and an air removal indicator placed in the center of the stack all placed within an exterior containment box. A process indicator label placed on the containment box alerts users if a pack has been exposed to the sterilization process. The approximate dimensions of the pack are 4-5/8" x 7/8" x 6-1/4"
Endpoint Color	Dark Brown/Black	Dark Brown/Black
Indicator Agent	Indicator Ink	Indicator Ink
Sterilization Method	Steam prevacuum	Steam prevacuum
Device Materials	Equivalent	Equivalent
Air Porosity	Equivalent	Equivalent
Performance under Complete reaction cycle	Equivalent	Equivalent
Performance under standard fault condition	Equivalent	Equivalent
Biocompatibility	Equivalent	Equivalent
Shelf Life	Three (3) years	Three (3) years
Post processing stability	Exceeds two (2) years	Exceeds two (2) years

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 5, 2014

SPSmedical Supply Corp.
Division of Crosstex International
Michael Nolan
Research and Development Coordinator
6789 West Henrietta Road
Rush, NY 14543

Re: K133204
Trade/Device Name: AirView™ II Bowie Dick Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator, Physical/Chemical Sterilization Process
Regulatory Class: II
Product Code: JOJ
Dated: March 24, 2014
Received: March 26, 2014

Dear Mr. Nolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

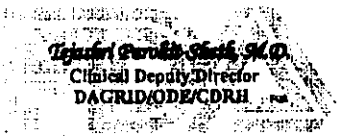
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K133204

Device Trade Name: AirView™ II Bowie Dick Test Pack

INDICATIONS FOR USE:

The AirView™ II Bowie Dick Test Pack is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C for 3.5 minutes. The indicator sheet within the AirView™ II Bowie Dick Test Pack will demonstrate a uniform color change from blue to dark brown/black when proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C (+1° /-0°C) temperature difference between the center of the towel pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the AirView™ II Bowie Dick Test Pack will demonstrate a non-uniform color change.

Prescription Use _____ and/or Over the Counter Use __X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300055864, cn=Elizabeth F. Claverie -S
Date: 2014.05.05 17:56:57 -04'00'